## **INJECTION SYRINGE**

## CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of U.S. application Ser. No. 07/750,416, filed Aug. 27, 1991 now abandoned.

## FIELD OF THE INVENTION

This invention relates to an apparatus and method for the injection of high viscosity liquids or pastes. The invention has particular utility as an injection syringe useful for injecting such liquids or pastes in surgical procedures, especially in endoscopic procedures, and will be described in connection with such utility, although other utilities are contemplated.

## **BACKGROUND OF THE INVENTION**

The present invention relates to an injection syringe, <sup>20</sup> particularly for medical purposes, for injecting high viscosity liquids or pastes. In particular, the present invention relates to an injection syringe suitable for endoscopic correction of vesicoureteral reflux.

Vesicoureteral reflux amounts to a reflux of urine 25 from the bladder into the ureter and predisposes an individual to damage of the upper urinary tract by bacterial infection and by increased hydrostatic pressure. Vesicoureteral reflux is most often due to a congenital malimplantation of the ureter into the bladder; incom- 30 plete development of the intramural ureteral tunnel causes a failure of the valvelike action at the ureterovesical junction and permits the reflux of bladder urine into the ureter and renal pelvis, particularly under the increased intravesical pressures of voiding. Other causes 35 of vesicoureteral reflux include bladder outlet obstruction with increased intravesical pressures, lower urinary tract infection with edema and distortion of ureteral orifice, neurogenic dysfunction of the detrusor and vesical neck mechanism, and iatrogenic reflux second- 40 ary to surgical or instrumental manipulation of the ureteral orifice. See, "The Merck Manual of Diagnosis and Therapy", Published by Merck Sharp & Dohme Research Laboratories (1977).

Treatment of reflux is either medical or surgical. 45 Medical management is based on the observation that vesicoureteric reflux tends naturally to improve with time. Surgical treatment generally entails opening the bladder and performing a variety of procedures on the ureter. An alternative method of treatment considers 50 intravesical injection of Teflon paste into the space behind the ureter. See, e.g. P. Puri and B. O'Donnell, The British Medical Journal, Vol. 289, July 1984; A. Farkas et al, The Journal of Urology, Vol. 144, August 1990.

Accordingly, injecting syringes have been developed to respond to the need for a delivery system which can readily inject the high viscosity substances described above. The known injecting syringes of this type are constructed inter alia with long injection cannula, 60 which are slightly elastic and can be introduced into a corresponding channel of an endoscope. One example of such a device is described in U.S. Pat. No. 4,276,878. See also U.S. Pat. Nos. 4,432,753; 4,020,838; 3,682,175; 3,353,537; 3,104,448; 2,821,195 and 1,982,993.

However, problems with the above designs include the relatively large diameter of the pistons required to advance the high viscosity material through a long and

relatively small diameter opening. Furthermore, earlier devices have not provided a means to continuously deliver high viscosity liquids or pastes without the need to continuously refill the particular piston chamber.

5 Finally, existing designs cannot be tailored to a variety of viscosities and pressures.

One extremely early attempt to develop a pumping mechanism that may have been suitable for adaption in an injection syringe of the type contemplated herein, was described in U.S. Pat. No. 731,033 (1903). This particular pumping mechanism included a tubular fluid-circulating chamber formed at one end with an inlet neck, and containing at its opposite end an outlet neck, wherein the inlet neck was fitted with an inwardly opening check valve permitting fluid to enter the circulating chamber and close in a direction to prevent backflow of fluid. The outlet neck was described as having an outwardly-opening check valve, to permit the discharge of fluid from the chamber under the input of a pumping action.

This particular design, however, made no mention of the fact (as described herein) that a ball-bearing type check valve, of varying durometer, in combination with adjustment of the inlet and outlet port size, together provides a pumping mechanism that "self-throttles", i.e. one in which the pumping action is restricted or rendered impossible over a certain desired and targeted range of internal delivery pressure.

Another early attempt to develop an injection syringe was reported in Australian Patent Specification 126,075 (1945). This particular design employed the use of a vertically mounted diaphragm which effected the actual displacement of liquid from a single an upper horizontal hollow chamber. However, it was specifically suggested that more complete piston designs would leak or stick and be more difficult to clean or provide a moving mechanism.

In U.S. Pat. No. 4,664,298 there is described a hand lever operated grease gun that has both high pressure and high volume modes afforded by changing the mechanical advantage of a lever acting on a dispensing piston. Although this particular reference also disclosed check valves in combination with a single piston for fluid delivery, it also failed to appreciate how important the selection of materials, and the size of the inlet and outlet ports were to the control of internal delivery pressure. Furthermore, unlike the present invention which uses single-arm control, this reference describes a dual-arm level action for fluid delivery.

Other related art, e.g. French Pat. 275017 and U.S. Pat. Nos. 2,709,025 and 1,982,993 describe fluid delivery systems, but none of these references solve the problem of providing a fluid delivery system for high viscosity pastes in the novel manner that is herein described.

Accordingly, it is an object of this invention to obviate these disadvantages and to provide an injection syringe that easily delivers a much higher pressure to fluid or paste, so that the fluid or paste is advanced with maximum reliability and avoids sticking in a piston chamber or cannula of the device.

It is a further object of this invention to provide an injection syringe wherein a high viscosity paste of fluid is continuously fed into a piston chamber so that a continuous source of fluid or paste can be delivered to a desired location within a body cavity.

It is also an object of this invention to accomplish the above through the convenience of operation of a pistol-